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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/842,466 | 04/26/2001 | Hiroyasu Kokubo | 35576/233803 | 8005 |
| 826 | 7590 | 09/22/2004 | EXAMINER | |
| ALSTON & BIRD LLP BANK OF AMERICA PLAZA 101 SOUTH TRYON STREET, SUITE 4000 CHARLOTTE, NC 28280-4000 | | | SHEIKH, HUMERA N | |
| | | ART UNIT | PAPER NUMBER | |
| | | 1615 | | |

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/842,466 | KOKUBO ET AL. | |
| | Examiner | Art Unit | |
| | Humera N. Sheikh | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 April 2004.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 6-9,11,13-20 and 31-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 6-9,11,13-20 and 31-47 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____. | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 CFR 1.114 and the request for extension of time (1 month-granted), both filed 03/29/04, Applicant's Remarks/Arguments, filed 04/27/04 and the Notice of Appeal filed 02/05/04 is acknowledged.

Claims 6-9, 11, 13-20 and 31-47 are pending. Claims 6, 7, 11 and 13-17 have been amended. New claims 31-47 have been added. Claims 6-9, 11, 13-20 and 31-47 are rejected.

Claim Objections

Claims 6, 7, 11 and 13-17 are objected to because of the following informalities:

The claims are objected to under 37 CFR 1.75 as being improper dependent claims. Claims must depend from a preceding claim to be in proper dependent form. Appropriate correction is required.

New Matter Rejection

Claims 33-47 are rejected because they introduce new matter to the claims. The phrase "Changing the coloration of one or more parts of the coating layer by irradiating those parts of the coating layer *to the exclusion of the remainder of the coating*" in Claim 33, lines 5-6, is not

supported by the instant Specification. Dependent claims 34-47 are also rejected under new matter since they are dependent on a rejected base claim. Clarification is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 6-9, 11, 13-17 and 31-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270).

Hampton *et al.* teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

The multiple characteristic tablet comprises different color sections, which includes a color demarcation line (22) extending traversely between the halves (14 & 18) of the core. The core (12) is preferably coated with a clear material (24). The coloring agents employed are conventional and any desired color combination can be employed (col. 3, lines 5-38).

A feature of the invention is to coat the bi-layer, two-colored tablet with a single coating of gelatin or a film-forming polymeric substance, which will simulate the appearance, and function of the gelatin capsule. Suitable film-forming materials include methylcellulose, hydroxypropyl methylcellulose, polyvinylpyrrolidone, ethylcellulose, various derivatives of methacrylic acids and methacrylic acid esters, and cellulose acetate phthalate (col. 5, lines 37-49). The coating of the film-forming polymer may be applied in several ways, such as by using conventional coating pans. Spray guns or other suitable atomizing equipment may be introduced into the coating pans to provide spray patterns conducive to rapid and uniform coverage of the tablet bed. The coating material is sprayed until the tablets are uniformly coated to the desired thickness and desired appearance of the tablet (col. 5, line 59 – col. 6, line 15).

The examples at columns 7-9 demonstrate two-colored, bi-layered capsule-shaped tablets. For instance, Example 1 demonstrates a bi-layered capsule-shaped tablet made from two separate layers, which were compressed together on a tablet press to form a tablet with an appearance similar to a capsule's appearance.

Instant claims are drawn to a solid preparation coated with a continuous film prepared by coating a solid preparation with a continuous film-coating layer having one or more colorants; and exposing a first part of the coating layer to a first amount of radiation and exposing a second

part of the coating layer to a second amount of radiation under conditions sufficient to result in the first and second parts of the coating layer having different coloration.

A product is being claimed in which the solid preparation comprises more than one distinct coloring agent. It is the position of the Examiner that the prior art expressly teaches a two-colored, bi-layered tablet formulation consisting of a first and second different coloring agent, wherein the tablet is provided with a single continuous coating layer and film-forming agents. The tablet of Hampton *et al.* is a multi-colored product having two layers wherein distinct colors with different color sections are provided for easy recognition of the tablet. The instant claims are product claims and it is the patentability of the product that must be established. There is no criticality observed in the process of forming the distinct coloration solid preparation, since the end result is a solid product having one or more different colors. As delineated above, the prior art explicitly teaches a tablet formulation having more than one distinct colors on the tablet.

Claims 18-20 and 45-47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hampton *et al.* (US Pat. No. 5,089,270) as applied to claims 6-9, 11, 13-17 and 31-44 above, and further in view of Hoover *et al.* (US Pat. No. 5,464,631).

Hampton *et al.* ('270), as discussed above, teach a multi-characteristic, bi-layered, two-color, capsule-shaped tablet consisting of a first and second different coloring agent and a blend of one or more excipients and active substances. The multi-colored tablet is coated with a clear coating, such as gelatin, to provide a solid medicament with the appearance of a gelatin capsule (see Abstract).

Hampton *et al.* teach color demarcation lines on the tablet. Hampton *et al.* do not teach the inclusion of patterns comprising logos, bar codes or letters.

Hoover et al. ('631) teach a two-colored medicament dosage form having embossed or debossed letters, logos, symbols and the like on the surface of the dosage form (see reference column 4, lines 37-44).

It would have been obvious to use the combined teachings of Hoover *et al.*, who teaches a two-colored medicament comprising embossed letters, logos, symbols and the like, within the formulation of Hampton *et al.* who teaches a two-colored tablet with distinct color demarcations because Hoover *et al.* teach that the embossed letters, logos and symbols provide for visual perception, brand name recognition and an aesthetic appearance of the dosage form. The expected result would be a distinct, visually improved solid dosage form for easier brand recognition.

Response to Arguments

Applicant's arguments with respect to claims 6-20 over US Pat. No. 4,820,524 ("Berta") have been considered but are moot in view of the new ground(s) of rejection.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

H. N. Sheikh 9/18.

Patent Examiner

Art Unit 1615

September 15, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600